DEPARTMENT OF HEALTH & HUMAN SERVICES

COPY

Public Health Service

m2334n

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

Telephone: 425-486-8788
FAX: 425-483-4996

January 14, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-05

Donald Giles, President
Icicle Seafoods, Inc.
4019 21st Avenue West
Seattle, Washington 98199

WARNING LETTER

Dear Mr. Giles:

On October 1, 16, and 21 - 23, 1998, investigators from the Food and Drug Administration (FDA) conducted an inspection of Port Chatham Packing Company located at 632 NW 46th Street, Seattle, Washington. At the conclusion of the inspection, Mykel A. Pierson, Production Supervisor, was presented with a FORM FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 113 - Low Acid Canned Food (LACF) Regulations. A copy of that FORM FDA 483 is enclosed for your review. By virtue of these deficiencies, the thermally processed products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our investigators found:

1. In September 1985 your firm began processing salmon and trout pate in 301 x 106, 307 x 113, and 307 x 200.25 cans under scheduled processes provided by [redacted]) and filed with the FDA. In November 1985 you reformulated the pate and obtained updated scheduled processes for salmon pate in 307 x 200.25 cans only. Apparently, you did not file those processes with the FDA because you continued to use the original processes, which were longer. However, in 1993 your firm again reformulated the pate, but continued to operate under the September 1985 scheduled processes for 301 x 106 cans and the November 1985 processes for 307 x 200.25 cans. Since 1993 and until the date of our inspection, your firm has been thermally processing salmon pate in 301 x 106 and 307 x 200.25 cans under scheduled processes that do not account for product reformulation. In a letter from [redacted] to your firm, dated November 19, 1985, your firm was notified as follows:

"... any change in can size or product formulation will require further work to determine product adequacy." CFR Part 113.83 requires scheduled processes to be established by a qualified individual.

2. Since July 11, 1996, all products processed in retort number two were processed while your firm was using an incorrect recorder chart for the recording/controlling instrument for that retort. Your firm was using an incorrect chart ([redacted]) that had a different temperature scale than the correct chart [redacted] that your firm should have been using. This is significant because the incorrect chart read approximately eight (8) degrees Fahrenheit lower than the correct chart. The use of an incorrect recorder chart caused your temperature recording device to be inaccurate and hampered your firm's ability to continually monitor the processing temperature. 21 CFR Part 113.40(a)(2) requires you to have an accurate temperature-recording device. Prior processing deviations caused by retort temperature drops, if any, may have been evaluated at a retort temperature higher than actual. Any process deviations caused by retort temperature drops after July 10, 1996 must therefore be re-evaluated by your processing authority.

The FDA acknowledges that during the inspection you began to take action to correct the above violations. However, we are gravely concerned that such egregious violations occurred at your firm for an extended period of time. Further, those violations most certainly would not have been found if not for FDA's inspection. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure, and/or injunction.

Within 15 working days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. Additionally, we request immediate written assurance from you and your process authority that the salmon pate and products processed in retort number two do not pose a health hazard to consumers. Pertinent Section of the Act and the Regulation are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, P.O. Box 3012, Bothell, Washington 98041-3012.

Sincerely,

Roger L. Lowell
District Director